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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,256	04/12/2000	Mylavarapu Venkatramesh	MTC 6462.1	6162

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/26/2003

2625

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/548,256

Applicant(s)

VENKATRAMESH ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-13, 17-19, 34-42, 46-48 and 70-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-13, 17-19, 34-42, 46-48 and 70-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All   b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 11, 24.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The rejection of Claims 2-6, 17-19, 34-35, 38-42, 46-48 and 70 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments to the claims.

The rejection of Claims 34 and 37 under 35 U.S.C. 101, is withdrawn in view of Applicant's amendments to the claims.

The rejection of Claims 1-12 under 35 U.S.C. 103, is withdrawn in view of Applicant's arguments.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor. Citizenship for the 2<sup>nd</sup> and 5<sup>th</sup> inventors are omitted.

### ***Claim Rejections - 35 USC § 112***

1. Claims 1-13, 17-19, 34-42, 46-48, and 70 remain rejected and newly added claims 71-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/22/2002. Applicants arguments filed 11/21/2002 have been considered but are not deemed persuasive.

Applicant asserts that they need not describe all things that are encompassed by the claims and that claims may be broader than the specific embodiment disclosed in the specification (response page 13). Applicant in order to meet the written description requirement must describe structural features that would distinguish the members of the claimed genus from non-members.

Applicant asserts that they have described the genus of recombinant DNA constructs by defining "structural features of the components of a recombinant construct" and Applicant has described the nucleic acid sequences of SEQ ID NO: 2, 4, and 8. (response page 14). Although Applicant describes a full length steroid 5 $\alpha$ -reductase nucleic acid from *Arabidopsis* and maize, Applicant fails to describe other nucleic acids from the broad category of steroid 5 $\alpha$ -reductase polynucleotide sequences, especially from non-plant organisms. Furthermore, Applicant fails to describe conserved structural motifs which are common among and unique to all nucleic acids of the broad category of steroid 5 $\alpha$ -reductase encoding polynucleotides.

2. Claims 1-13, 17-19, 34-42, 46-48, and 70 are rejected and newly added claims 71-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, is enabling only for claims limited to recombinant constructs comprising *Arabidopsis* and corn cDNAs encoding steroid 5 $\alpha$ -reductase of SEQ ID NO: 2 and 4, as well as transformed host cells, transgenic plants and seeds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/22/2002. Applicants arguments filed 11/21/2002 have been considered but are not deemed persuasive.

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Applicant asserts that the specification does indeed disclose how to make the claimed invention by listing common molecular biological procedures useful for making the invention and that no undue burden with respect to experimentation would be required for one of skill in the art (response pages 15-16). While molecular biological techniques were known in the art, Applicant fails to provide specific guidance for isolation of additional steroid-5 $\alpha$ -reductase nucleic acids encompassed by the broad scope of the claims, i.e. Applicant provides no guidance for probe or primer sequences, hybridization/wash conditions or PCR reaction conditions that would allow specific isolation of steroid 5 $\alpha$ -reductase nucleic acids. In the absence of such guidance, undue trial and error experimentation would be required to screen through the myriad number of DNA clones from any and all organisms to isolate other nucleic acids that encode steroid-5 $\alpha$ -reductase.

Applicant asserts that the office action suggested a requirement for *a priori* predictability without recourse to any experimentation and that there is no legal requirement that each and every steroid 5 $\alpha$ -reductase be useful for each and every contemplated utility (response pages 17-18). Applicant has not defined the broadly claimed genus of polynucleotides that would encode a steroid 5 $\alpha$ -reductase. Applicant provides no guidance for probe or primer sequences, hybridization/wash conditions or PCR reaction conditions that would allow specific isolation of steroid 5 $\alpha$ -reductase nucleic acids. In the absence of such guidance, undue trial and error experimentation would be required to screen through the myriad number of DNA clones from any and all organisms to isolate other nucleic acids that encode steroid-5 $\alpha$ -reductase. Given the failure of the broadly claimed genus of polynucleotides that would encode a steroid 5 $\alpha$ -reductase to be adequately described, methods of use are also inadequately described. See Written

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Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111. See also *Genentech, Inc. v. Novo Nordisk*, A/S 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply enabling aspects of the invention.

***Claim Rejections - 35 USC § 101***

3. Claim 35 and 41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/22/2002. Applicants arguments filed 11/21/2002 have been considered but are not deemed persuasive. Claims 35 and 41 recite "Progeny of a plant, the genome of which comprises introduced DNA" and does clarify whether or not the progeny comprise said DNA.

***Claim Rejections - 35 USC § 102***

4. Claims 1, 7-12 remain rejected and newly added claims 71 and 77-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (PNAS Vol. 34, pp.3555-3559, April 1997). This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/22/2002. Applicants arguments filed 11/21/2002 have been considered but are not deemed persuasive.

Applicant asserts that the cited reference does not teach the sequence of a steroid 5 $\alpha$ -reductase nucleic acid and thus the reference does not anticipate all of the elements of the

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claimed invention (response page 21). The nucleotide sequence encoding an *Arabidopsis* steroid 5 $\alpha$ -reductase is taught by reference to DET2 (Li J. *et al.* PNAS, April 1997, Vol. 94 on page 3554 column 1, lines 7-21) a common genetic reference that allows for easy access to the nucleotide and amino acid sequences submitted to GenBank on the 8<sup>th</sup> of April, 1996 under Accession numbers U53860 for the polynucleotide sequence and AAC49264 for the amino acid sequence. Further, Applicant has already, by reference, incorporated this sequence into the specification on page 100 in Example 2, thus providing an admission that it has been taught prior to the date of claimed priority.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.  
February 6, 2003



**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
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